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10/783,628	02/20/2004	Ricardo E. Paxson	MWS-108RCE	7206
74321 7590 10/29/2008 LAHIVE & COCKFIELD, LLP/THE MATHWORKS FLOOR 30, SUITE 3000 One Post Office Square Boston, MA 02109-2127				
EXAMINER ZHOU, SHUBO				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/783,628

**Applicant(s)**

PAXSON ET AL.

**Examiner**

SHUBO (Joe) ZHOU

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/16/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draft Person's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's request for reconsideration in the response filed 7/16/08 is acknowledged.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are currently pending and under consideration.

#### ***Withdrawn Rejection***

The provisional rejection of claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 45-47 of US copending Application No. 10/783624 in view of Kelly et al. (IDS document: WO 03/001891, 09 January 2003) is withdrawn in view of the Terminal Disclaimer filed 7/16/08, which is approved.

#### ***Claim Rejections-35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated from the previous Office action.

The claims are drawn to a process, system or article of manufacture for modeling and simulation of a biological process comprising constructing a model of the biological

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process, generating and display dynamic behavior of the modeled biological process (as in claim 8, etc.) or analyzing the constructed model to generate a result and transmitting the result to the modeling component (as in claim 20, etc.).

The claimed invention involves computational algorithm, which is a judicial exception. The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at

<http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a final result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete," the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to

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statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not produce a useful result. It appears that the claimed invention, e.g. claim 1, generates "dynamic behavior" for a biological process as final result. However, a detailed search of the specification does not provide adequate description as to what "dynamic behavior" is. The specification does not assert a specific, substantial and credible use for the "dynamic behavior" generated. One skilled in the art would realize that dynamic behavior could vary with each biological process. Simply generically providing dynamic behavior without detailing what they are (no specific example given in the specification) falls short of a specific and substantial use therefor as one skilled in the art would have to perform further research to find out what the behavior is and correlates to and determine any practical utility therefor. Therefore, the claimed invention does not produce a useful and concrete and tangible result.

Furthermore, claims 15-18, 40-43, and 77-81 are now amended to be drawn to an article of manufacture comprising computer instructions. Thus, the claims are drawn to a computer readable medium comprising computer instructions. While the instant specification does not explicitly define the scope of the limitation of "computer readable medium," one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fickowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being "a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave." See column 14, claim 12. Bornstein et al., in US patent 6,1443,88 (Date of patent : Nov. 7, 2000) state, "The computer readable medium of the

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present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave.” See column 8, lines 33-37.

Therefore, at least one embodiment of the claims is drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. The following analysis on why such a signal encoded with functional descriptive material is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>):

*First, a claimed signal is clearly not a "process" under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures "relate to structural entities and can be grouped as 'product' claims in order to contrast them with process claims." 1 D. Chisum, Patents §1.02 (1994). The three product classes have traditionally required physical structure or material.*

*"The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and*

*computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.*

*A "composition of matter" "covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff'd, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.*

*The Supreme Court has read the term "manufacture" in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.*

*A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that a manufacture was also intended to require physical matter. A signal, a form of energy, does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.*

[.....]

*These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.*

Thus, the claims are drawn to nonstatutory subject matter.

With regard to claims 26-30 and 64-67, drawn to a system, because the method claims do not produce a useful, concrete and tangible result and are thus drawn to nonstatutory subject matter, the system claims for performing the process do not produce a useful, concrete and tangible result for the same reasons.

Applicant's arguments filed 7/16/08 have been fully considered but they are not persuasive. Applicant argues that the claims produce a useful result and refers to page 23 and pages 5-6 of the specification. See pages 3-4 of the response. However, the specification on page 23 discusses the need for simulating all significant behavior such as the path of a bouncing ball, and the specification on pages 5-6 discusses that the simulation engine generates dynamic behavior. However, the specification does not assert a specific, substantial and credible use for dynamic behavior of a modeled biological process.

As to claims 15-18, 40-43, and 77-87, drawn to a article of manufacture, applicant merely argues that article of manufacture is well established as being statutory, but does not specifically argues against the examiner's position that the article of manufacture includes computer readable medium that in turn includes carrier wave, which is a signal, which is nonstatutory subject matter. See page 4 of the response.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.



This rejection is reiterated from the previous Office action.

As set forth above, the instant claims do not produce a useful result. It appears that the claimed invention, e.g. claim 1, generates “dynamic behavior” for a biological process as final result. However, a detailed search of the specification does not provide adequate description as to what “dynamic behavior” is. The specification does not assert a specific, substantial and credible use for the “dynamic behavior” generated. One skilled in the art would realize that dynamic behavior could vary with each biological process. Simply generically providing dynamic behavior without detailing what they are (no specific example given in the specification) falls short of a specific and substantial use therefor as one skilled in the art would have to perform further research to find out what the behavior is and correlates to and determine any practical utility therefor. While certain method of modeling and simulation of a biological process may have patentable utility, the claimed process does not because there is asserted specific, substantial and credible utility or a well established utility for the claimed process comprising the recited steps.

Applicant presents the same argument as above, which is not persuasive for the same reasons set forth above.

### *Claim Rejections-35 USC § 112*

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 112, first paragraph.

This rejection is reiterated from the previous Office action.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's argument is nonpersuasive because the arguments for the utility rejection was not found persuasive for the reasons set forth above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. (IDS document: WO 03/001891, 09 January 2003).

This rejection is reiterated from the previous Office action.

The claims are drawn to a method, system or article of manufacture for modeling and simulation of a biological process, the method comprising constructing a model of the biological process, generating and display dynamic behavior of the modeled biological process (as in claim 8, etc.) or analyzing the constructed model to generate a result and transmitting the result to the modeling component (as in claim 20, etc.).

Kelly et al. disclose a method and system for modeling and simulation of immune system including various biological processes. The method comprises providing data using graphical user interface and constructing a model of the immune system comprising components of immune responses using various mathematical equations including stochastic differential equations and Effect Diagram (see at least pages 9, 15), validating

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the model and using the model to produce simulated biological attributes associated with the biological state of the immune responses and compare simulated biological attributes with a corresponding biological attribute of a reference pattern of the immune response, which simulated biological attributes are interpreted as being dynamic behavior of the modeled process. See at least Fig. 3 and pages 43-44. These are displayed in the various drawings disclosed by Kelly et al.

Kelly et al. do not explicitly teach modifying the constructed models by user commands received through both a graphical user interface and a textual interface.

However, Kelly et al. do state on page 11 that their “model can be modified to reflect .... The regions of interface can, for example, include ....” This indicates that their model can be identified and interface is used. Kelly et al. disclose that the computer system used for their modeling comprises a video display on which a user interface is displayed, which is interpreted as a graphical interface, and a network interface, which is interpreted as a textual interface. Considering Kelly et al. disclose that their model can be executed by computer-executable software code representing dynamic biological processes including adaptive immune response (see page 8), it would be readily apparent to one skilled in the art that the model can be constructed or modified by receiving computer executable instructions received through the graphical and textual interfaces.

Furthermore, as the modeling, simulation and validation are also performed in computer systems with monitors and other display devices, all the results would be inherently displayed in the display devices involved. The Effect Diagram used in the modeling is considered a block diagram. Kelly et al. also disclosed the computer system

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and computer programs including codes for executing the method of modeling and simulations. See at least pages 41-42.

Therefore, one of ordinary skill in the art would have been motivated by Kelly et al. to modify their models as suggested by them in order to improve. Given Kelly et al. provide both graphical and textual interface, it would have been obvious that the commands from the user to modify the model would have been through either or both the graphical and the textual user interface.

Applicant's arguments filed 7/16/08 have been fully considered but they are not persuasive. Applicant first argues that Kelly et al. fails to teach or suggest that the constructed model is modified by user commands received through both a graphical user interface and a textual interface that is separate from the graphical user interface. Applicant further argues that the user interface on the video display is not a graphical user interface. See page 7 of the response. This is not found persuasive because it would be readily apparent to one of ordinary skill in the art that an interface on a video display would inherently be a graphical interface. Applicant also argues that Kelly does not teach or suggest the network interface device is used to receive user commands to modify a model but rather to receive software. This is not found persuasive. As set forth in the previous Office action and reiterated above, Kelly et al. encourage modifying their model. It would have been obvious to one of ordinary skill in the art that in order to modify the model, commands would have to be transmitted and that an obvious route to transmit such commands would have been via the network interface device.

### ***Conclusion***

No claim is allowed.

#### **THIS ACTION IS MADE FINAL.**

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center

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supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER